**REMARKS:**

**Claims 1 and 60**

The Examiner has rejected claims 1, 2, 6-8 and 41, 43-45, 47, 48, 51, 53, 54 and 58 under 35 USC 103 as being made obvious over WO 93/11817 to O'Callaghan in view of an article entitled "Conductive Plastics for Medical Applications" authored by Larry Rupprecht and Connie Hawkinson (hereinafter "Rupprecht et al."). The Examiner also has rejected claims 3, 4, 11, 12, 17, 19, 49, 50, 55 and 57 under 35 USC 103 as being made obvious over O'Callaghan and Rupprecht et al. in view of U.S. Patent No. 6,345,617 to Englebreth et al. Applicants respectfully submit that the claims are allowable over the cited references for at least the following reasons.

First, independent claim 1 recites "a one-way valve disposed adjacent said output end, said one-way valve moveable between an open position and a closed position, wherein said one-way valve has a central opening when in said open position, said central opening defining a flow path along said longitudinal axis, *wherein no portion of said interior surface of said patient interface component downstream of said one-way valve intersects said flow path in an orthogonal relationship.*" Claim 59 further recites that the patient interface component is a mouthpiece, and claim 60 recites that the interior surface of the mouthpiece is *not antistatic*. Support for these amendments is found throughout the specification, including without limitation page 6, lines 10-14, page 7, line 25 to page 8, line 2, page 10, lines 1-9 and FIGS. 6, 7 and 9.

In this way, the medicament traveling along the flow path after it passes through the one-way valve during inhalation is not impacted upon an orthogonal surface (see, e.g., FIGS. 6, 7 and 9). This can be especially beneficial when the interior surface defining the flow passage downstream of the one-way valve is *not* antistatic, as recited for example in claim 60.

In contrast, neither O'Callaghan nor Engelbreth discloses a one-way valve at the downstream end of the spacer. Moreover, as shown in FIG. 1 of O'Callaghan, the mouthpiece 8 has an *orthogonal* interior surface *intersecting the flow path* of the outlet passage 7 of the spacer. The orthogonal portion of the interior surface of the mouthpiece 8 imposes an impact surface in direct communication with the flow path, which can exacerbate the attraction of medication particles (O'Callaghan at FIG. 1).

This is especially true if the interior surface of the mouthpiece 8 of O'Callaghan, which forms the orthogonal surface, is not antistatic, as recited in claim 60. Indeed, perhaps to alleviate such a concern, O'Callaghan discloses that the "mouth pieces may be formed from [anti-static] plastics" (O'Callaghan at 4).

For at least these reasons, claims 1 and 60, and any claims depending therefrom, are patentable over the cited references.

**Claims 7, 21 and 41**

Claims 7 and 21 depend from claim 1 and are patentable for at least the reasons set forth above. Claim 7 further recites that "at least a portion of said holding chamber is see-through," and claim 21 recites that "at least a portion of said holding

chamber and said second antistatic component is see-through." Likewise, independent claim 41 recites "an antistatic holding chamber comprising a see-through material having a surface resistivity of less than about 10E12 ohm/sq."

The citation in Rupprecht et al. at page 9, wherein it is stated that "a number of conductive thermoplastic compounds retain transparency while exhibiting static-control properties," actually teaches away from Applicants' invention when Rupprecht et al. is considered in its entirety. In particular, Rupprecht et al. discloses that "contact clarity – the ability to read objects through a directly contacting plastic material – is a desirable property that can be achieved in packaging applications, enabling bar code imprints or laser markings to be accurately detected and read by automatic equipment," and further that "contents of packages can also be identified by color coding, without violating the package seal" (Rupprecht et al. at 9).

In contrast, the holding chamber, or other antistatic component, of Applicants' invention is not used as a packaging component or application, and there is no reason for the user to be able to read through the material as disclosed in Rupprecht et al. Indeed, the motivation to make the spacer of O'Callaghan "see-through" is only achieved through hind-sight analysis of the present invention. In particular, as taught by Applicants, the plastic material "can be made see-through, such that the user or caretaker can monitor and visualize the interior of the holding chamber and/or component," for example to check for foreign objects or to monitor the flow of medicament (Specification at 3, lines 15-18). In contrast, nowhere does O'Callaghan

disclose or suggest the need for a see-through spacer, and the Examiner has not cited to any prior art suggesting the need or desire for such a feature. For at least these reasons, claims 7, 21 and 41, and any claims depending therefrom, should be passed to allowance.

**Claims 3, 11 and 49**

Claims 3 and 11 depend from claim 1, and claim 49 depends from claim 41. Accordingly, claims 3, 11 and 49 are patentable for all of the reasons set forth above.

Claims 3, 11 and 49 further recite an antistatic backpiece. As recognized by the Examiner, O'Callaghan does not disclose a separate backpiece (Office Action at 5-6). Instead, the Examiner asserts that it would have been "obvious to one of ordinary skill in the art at the time of the invention to modify the holding chamber of O'Callaghan with a backplate" (Office Action at 6). The Examiner never asserts, however, that it would furthermore have been obvious to one of ordinary skill in the art to also make the backpiece *antistatic* as recited in claims 3, 11 and 49. Applicants respectfully submit that the noted rejections should be withdrawn on this basis alone.

Notwithstanding this deficiency, Applicants respectfully submit that the references do not provide any suggestion to make such a backpiece antistatic. In particular, as shown in FIG. 1 of O'Callaghan, the shaped holder 6 extends into the spacer past the rear wall of the spacer. Accordingly, the rear wall, if made as a separate backpiece as disclosed by Englebredth, is positioned *upstream* of the release of medicament from the holder 6 of O'Callaghan. Accordingly, such a backpiece is

not exposed to the direct flow of medication and there is no suggestion, therefore, that it need be made of an antistatic material. Indeed, O'Callaghan discloses that the drug particles are "attracted to the sidewalls of the chamber" (O'Callaghan at 2). Accordingly, claims 3, 11 and 49 are patentable for at least this additional reason.

**CONCLUSION**

If this case is not considered in condition for allowance, and an interview would be helpful to resolve any questions the Examiner may have, Applicants respectfully invite the Examiner to contact the undersigned attorney at (312) 321-4713.

Respectfully submitted,

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